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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/912,774	07/25/2001	Manaud Pierre Frederic De Raspidé	PC10915A	5154

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Paul H. Ginsburg
Pfizer Inc
20th Floor
235 East 42nd Street
New York, NY 10017-5755

EXAMINER

PULLIAM, AMY E

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 01/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/912,774

Applicant(s)

DE RASPIDE ET AL.

Examiner

Amy E Pulliam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Receipt of Papers

Receipt is acknowledged of the Election, received by the Office on October 23, 2002.

Election/Restrictions

Upon reconsideration, the restriction requirement has been withdrawn and all claims are pending in the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13 and 14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Upon close examination of the instant specification, the examiner finds that the additional coating discussed in applicant's specification is actually a protective coating, used for the purpose of creating a smooth surface. (See applicant's specification, page 7, lines 23-30). Therefore, this additional coating would be found outside the first coating layer. Alternatively, applicant's claim language recites that the additional layer is inserted between the core and the first coating. There is no support in the specification for this specific formulation, and therefore, applicant is not enabled for the composition in claims 13 and 14.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 32-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims state a method of preventing, and it is unclear to the examiner what is meant by prevent. It is the position of the examiner that the word prevent implies a cure, and to the present date, there is no cure for migraines recurrence, only treatments. The claims would be more correctly phrased to state a method of treatment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12, 15-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 436 370 to Noda *et al.* in view of WO 00/32589 to Dallman *et al.*.

Noda *et al.* disclose a controlled release pharmaceutical preparation comprising a core containing a pharmaceutically active substance and a coating film formed on the surface of the core by aqueous coating of a water insoluble and slightly water permeable acrylic polymer containing a trimethylammonium-ethyl group. Noda *et al.* teach that the formulation of their invention can inhibit the dissolution and release of the pharmaceutically active substance for a

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fixed period of time and can rapidly release the active substance after the initiation of dissolving and releasing thereof (c 2, l 1-5). This release pattern fits the description of sigmoidal release. Examples of the coating composition to be used is a combination of Eudragit RL and Eudragit RS (c 2, l 50 – c 3, l 8). Noda *et al.* teach that the core to be coated may be granules, having an average particle size of about 300 microns to 2000 microns (c 3, l 20-25). Noda *et al.* also teach that the core can incorporate other conventional additives, such as excipients (lactose), binding agents (PEG and starches), lubricants and the like (c 3, l 45-60). The reference also teaches that the coating composition may include further excipients such as plasticizers (triethyl citrate) and agglomeration inhibitors (titanium dioxide) (c 5, l 18-34). Noda *et al.* also teach two different methods for forming the core. The first method involves mixing the active together with the excipients to form a granules. Alternatively, the active agent and excipients can be coated onto an inert core to form the core (c 4, l 18-42). Lastly, Noda *et al.* teach that their invention can be used with any active agent which can be administered orally (c 3, l 26-40) and that the composition can be administered as such, or in the form of capsules filled with the granules (c 9, l 15-19).

Noda *et al.* does not specifically teach eletriptan as the active agent to be used in the formulation, nor do they teach that eletriptan is useful in the treatment of migraines.

Dallman *et al.* discussed dosage suitable forms comprising eletriptan hydrobromide monohydrate. Dallman *et al.* teach that the active agent can be administered orally, in the form of tablets (p 4, l 18-19). Dallman *et al.* also teach that the active agent is useful in the treatment of migraines.

It is the position of the examiner that one of ordinary skill in the art would have been motivated to use eletriptan in the formulation described by Noda. Noda *et al.* teach a new type of formulation, which has a particular release pattern, and which is useful for any active which can be administered orally. Dallman *et al.* teach that eletriptan can be administered orally and is useful in treating migraines. Therefore, one of ordinary skill in the art would expect a successful pharmaceutical formulation comprising eletriptan cores with an outer coating, thereby achieveing the initial delay of release of the later rapid release of the active agent. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1, 2, 4-9,15, 17, 18, 20-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over "An Organix Acid Induced Sigmoidal Release System for Oral Controlled Release Preparations" by Narisawa *et al.* in view of Dallman *et al.*

Narisawa *et al.* disclose that a siogmoidal release system was developed in order to achieve a time controlled or site specific drug delivery in the GI tract. Sigmoidal relaease achieves a prolonged lag time followed by rapid release. Narisawa *et al.* teach that the formulation is prepared by making uncoated beads, comprising a mixture of the drug and excipients, and spraying this composition onto an inert non-pareil bead. The beads are then coated by spraying with a mixture of Eudragit RS, talc, triethyl citrate and water. The beads are approx. 1100 microns and the coating is about 90 microns.

Narisawa *et al.* do not teach the use of eletriptan specifically in the formulation, nor do they teach the use of eletriptan for the treatment of migraines.

Dallman *et al.* discussed dosage suitable forms comprising eletriptan hydrobromide monohydrate. Dallman *et al.* teach that the active agent can be administered orally, in the form of tablets (p 4, l 18-19). Dallman *et al.* also teach that the active agent is useful in the treatment of migraines.

It is the position of the examiner that one of ordinary skill in the art would have been motivated to use eletriptan in the formulation described by Narisawa *et al.*. Narisawa *et al.* teach a new type of formulation, which has a particular release pattern, and which is useful for any active which can be administered orally. Dallman *et al.* teach that eletriptan can be administered orally and is useful in treating migraines. Therefore, one of ordinary skill in the art would expect a successful pharmaceutical formulation comprising eletriptan cores with an outer coating, thereby achieving the initial delay of release of the later rapid release of the active agent. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A. Pulliam
Patent Examiner/ AU 1615
January 9, 2003


TRUMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600